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(54) AEROSOL COMPOSITIONS

(71) I, VOLKER FRITZ WILLY GILDEMEISTER of 25 Wyche Road, Malvern, Worcs., a British subject, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The present invention relates to an anti-smoking appliance.

In accordance with the invention there is provided an anti-smoking appliance comprising an aerosol dispenser containing a solution or dispersion of nicotine or a physiologically acceptable acid addition salt thereof (and no other alkaloid) and an essential oil or extract thereof in an aerosol propellant vehicle.

The aerosol dispenser is preferably fitted with a metering valve which delivers a fixed dose of the dispersion at each operation and can if desired include a device for directing the spray from the spray nozzle of the dispenser towards the mouth of the user. In each dose of the dispersion the amount of nicotine is desirably in the range of from 0.1 to 10 milligrams. Appropriate kinds of aerosol dispenser are known and have been used previously, for example, for administration of broncho-dilators in the treatment of asthma.

The nicotine may be present as such or may be in the form of a physiologically acceptable acid addition salt such as the dihydrochloride, salicylate, sulphate, or bitartrate. It is usually present in the dispersion in an amount of up to 0.2 per cent by weight. An alcohol such as ethanol, n-propanol, iso-propanol or ethylene glycol which is miscible with the propellant is usually present to dissolve the nicotine and render the dispersion uniform. An essential oil is present to impart an acceptable flavour to the solution or dispersion and to counteract the searing taste of any alcohol present; suitable essential oils include methol and peppermint oil. A surprising and desirable modification to the flavour of the composition may be produced by further incorporation therein of

glycerol and/or an artificial sweetener such as saccharin. Suitable propellants include chlorofluorinated methanes and ethanes having appropriate boiling points. The composition may additionally comprise an anti-oxidant or preservative.

The appliance preferably delivers a dose of about 0.1 mg. of nicotine in each operation in the form of a spray for inhalation by the user. The nicotine in the spray acts as a substitute for the nicotine which the user would normally obtain from cigarette smoke. The user therefore has to overcome only his psychological reasons for smoking, and is not further provoked by his physiological craving for nicotine. In addition, use of the appliance provides a distraction for the user which can to some extent replace the physical actions involved in smoking a cigarette. The dose of nicotine delivered at each operation may, if desired, be increased or reduced appropriately from the quoted figure.

The appliance will normally be used relatively frequently during an initial period, but after about 7 to 10 days use will become less frequent and can be discontinued after an appropriate period, generally about 21 days.

The invention is illustrated by the following Examples:—

Example 1

An aerosol dispenser was filled with the following composition (parts by weight):

| | |
|--|-------|
| Nicotine | 0.20 |
| Menthol | 0.10 |
| Absolute ethanol | 49.70 |
| Propellant (a mixture of "Freon" 12 and "Freon" 114 in a weight ratio 40:60) | 50.00 |

The dispenser delivered an appropriate dose of nicotine at each operation in the form of a spray for inhalation by a smoker. The flavour properties of the above composition were surprisingly more acceptable than those of a similar composition in which the menthol was omitted. (The word "Freon" is a Registered Trade Mark).

Example 2

A base composition was formed by mixing together the following ingredients (parts by weight)

| | | |
|---|--------------|------|
| 5 | Nicotine | 0.67 |
| | Methol | 3.00 |
| | Glycerol | 1.00 |
| | Abs. ethanol | 1.00 |
| | Saccharin | 0.20 |

10 An aerosol dispenser was filled with 7.5 gm. of the base composition and 17.5 gm. of "Freon" 12. The dispenser was equipped with a metering valve which delivered at each operation a 100 mg. aliquot of the resulting composition. The resulting aerosol spray has on

15 administration an acceptable flavour, whereas a similar composition in which the glycerine and saccharin are absent has an unpleasant searing taste.

20 I am aware of the Poisons Rules 1972 (1972 S.I. No. 1939) which relate *inter alia* to the sale of compositions containing nicotine, and I make no claim to the use of the invention in contravention to the said Rules.

25 Subject to the foregoing disclaimer,
WHAT I CLAIM IS:

1. An anti-smoking appliance comprising

an aerosol dispenser containing a solution or dispersion of nicotine or a physiologically acceptable acid addition salt thereof (and no other alkaloid) and an essential oil or an extract thereof in an aerosol propellant vehicle.

2. An appliance according to claim 1 which is fitted with a metering valve which delivers a fixed dose of the solution or dispersion at each operation.

3. An appliance according to claim 2 which is fitted with a metering valve which delivers a dose of the solution or dispersion containing about 0.1 mg. of nicotine.

4. An appliance according to claim 1, 2 or 3, wherein the essential oil extract in the solution or dispersion is menthol.

5. An appliance according to any preceding claim wherein the solution or dispersion additionally comprises glycerol and/or an artificial sweetener.

6. An appliance according to claim 1 substantially as hereinbefore described in Example 1 or in Example 2.

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